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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,027

Applicant(s)

SUN ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7, 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. Applicant's election with traverse of group III, claims 10-1, with respect to SEQ ID NO: 4, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that a restriction requirement/lack of unity was not made in the PCT application and therefore Applicants assert that the inventions of each of the recited groups have already been examined. This is not found persuasive because unity of invention can be broken at any stage of prosecution, including when an application enters the National Stage of prosecution (see MPEP 1893.03(d)).

The requirement is still deemed proper and is therefore made FINAL.

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Because claim does not recite a purity or size limitation, the claim reads on naturally occurring antibodies that bind with the polypeptide encoded by SEQ ID NO: 4.

Such antibodies are products of nature and are not patentable. To overcome this rejection it is suggested that the claims be amended to include purity limitations which would distinguish the claimed compounds, as enabled by the specification, over the naturally occurring compounds.

For example, this rejection may be overcome by amendment of the claims to include the terminology "isolated" and/or to provide a description of what the claimed products are "free of" relative to that of the natural source.

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3. Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-12 are indefinite over the recitation of “an antibody against a BSG wherein said BSG comprises....Mam004 (SEQ ID NO: 4)...” Since SEQ ID NO: 4 is a mRNA molecule, it is unclear as to whether the claims intend to refer to antibodies that bind with the mRNA of SEQ ID NO: 4 or to antibodies which bind with the protein encoded by SEQ ID NO: 4. It is also unclear as to what is intended to be meant by antibody “against” SEQ ID NO:4 since this term is vague and does not clearly set forth the relationship between an antibody and a ligand. It is suggested that claim 10 be amended to recite, for example, “An isolated antibody that specifically binds with the polypeptide encoded by SEQ ID NO: 4.”

Claims 11-12 are indefinite because the claims are drawn to a method of imaging breast cancer, but the claims do not recite active process steps which result in imaging breast cancer. That is, the claims recite a single step of administering an antibody but do not clarify how this step of administering an antibody results in imaging breast cancer. While the specification (see for example pages 6 and 14) teaches that an increase in Mam004 is correlated with the occurrence of breast cancer and teaches that the amount of labeled antibody can be used to diagnose the presence or absence of breast cancer in vivo or can be used to determine whether the extent to which the disease has spread, the claims themselves do not clarify how the single step of administering an antibody results in the imaging of breast cancer.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

January 13, 2003

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER